

REMARKS

The present application includes claims 1-4, 6-9, and 12-20. Claims 1-9 and 12-20 have been rejected. By this Response, claim 5 has been canceled, and claims 1, 8, and 14 have been amended.

Claim Amendments

Claim 1 has been amended to recite that the tracking system measures one or more locations on the instrument using the sensor and the plurality of fiducials in closed form registration to calibrate the instrument, thereby incorporating the limitations of canceled dependent claim 5. Additionally, the tracking system has been amended to recite a feedback mechanism used during surgical navigation to determine accuracy of tracking of the instrument by comparing tracked versus actual instrument position to determine whether positional accuracy is within a certain tolerance and recalibrating the instrument during surgical navigation if the positional accuracy is outside the certain tolerance.

Claim 8 has been amended to recite the additional steps of 1) obtaining feedback during surgical navigation to determine accuracy of tracking of the instrument by comparing tracked versus actual instrument position to determine whether positional accuracy is within a certain tolerance; and 2) recalibrating the instrument during surgical navigation if the positional accuracy is outside the certain tolerance.

Claim 14 has been amended to recite the additional steps of 1) obtaining feedback during the image-guided operation to determine accuracy of tracking of the instrument by comparing tracked versus actual instrument position to determine whether positional accuracy is within a

certain tolerance; and 2) recalibrating the instrument during image-guided operation if the positional accuracy is outside the certain tolerance.

The Applicant submits that amended claims 1, 8, 14, and their dependent claims should be allowable over the cited art of record.

Provisional Double Patenting

Claims 1-20 (should now read claims 1-4, 6-9, and 12-20) have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 7-20 of copending Application No. 10/962,019, a continuation-in-part of the present application. The Examiner submits that claim 1-20 involve an obvious variation of copending claims 7-20 claiming substantially identical subject matter. While the Applicant agrees that the claimed subject matter is related, the Applicant submits that the two claim sets are still patentably distinct, with claims 1-20 generally directed to systems and methods for closed form registration, feedback, and recalibration of an instrument, while claims 7-20 of the copending application generally directed to systems and methods using projective techniques to account for object rotation in an object, such as an implant or part of a patient anatomy. Since the rejection is a provisional rejection, the Applicant reserves the right to further traverse the double patenting rejection once one of these claim sets has been allowed.

Rejections under 35 U.S.C. §103

Claim 1-20 (should now read claims 1-4, 6-9, and 12-20) were rejected under 35 U.S.C. 103(a) as being unpatentable over Krause et al. (U. S. Patent No. 6,711,342) in view of Krause et al. (U. S. Patent no. 6,701,174).

As previously discussed, Krause '174 relates to computer-assisted orthopedic surgery planner software for generation of 3D solid bone models from 2D X-ray images of a patient's bone. See, e.g., Abstract and col. 1, ll. 15-20. Krause '174 involves no tracking and is used for remote training and pre-surgery guidance to a surgeon, rather than to calibration of an instrument as recited in claim 13. See, e.g., Abstract and col. 3, ll. 9-11. Additionally, in Krause '174, rather than adjusting tracking based on variation between a computer-generated or mathematical model and a measured physical model, as recited in independent claim 8, Krause '174 adjusts a 3D template based on 2D patient images. See, e.g., col. 5, ll. 13-25. Note that Krause '174 uses the word "deform" to indicate an adjustment or modification of a 3D template model based on observed data. The template model of Krause '174 is a very general geometric model that is refined based on bone contours identified through processing of 2D images of the particular bone. See, e.g., col. 12, ll. 4-62. As defined in Krause '174, "[d]eformations allow the user to treat a solid as if it were constructed from a special type of topological putty or clay which may be bent, twisted, tapered, compressed, expanded, and otherwise transformed repeatedly into a final shape." Col. 12, ln. 66 – col. 13, ln. 24. Thus, Krause '174 clearly intends a different use of deformation on a general, geometric, volume-based putty model rather than obtaining a plurality of measurements for an instrument after the instrument has been deformed. Again, Krause '174 does not measure an instrument and does not accommodate deformations of the instrument as described, for example, in the present application.

In an effort to further clarify for the Examiner the distinctions between Krause '174 and the presently pending claims, independent claim 1 has been amended to specify use of *closed form registration* to calibrate the instrument, a technique not found in Krause '174. Additionally, independent claims 1, 8, and 14 have been amended to recite systems and methods

for obtaining *feedback* during operation to determine accuracy of tracking of the instrument by comparing tracked versus actual instrument position to determine whether positional accuracy is within a certain tolerance, and *recalibrating* the instrument during operation if the positional accuracy is outside the certain tolerance.

Additionally, as previously discussed, the Krause '432 patent uses software to generate a three-dimensional model of an area of a patient upon which a surgical procedure is to be performed using a template database but fails to provide any teaching or suggestion of using that template in comparison to a current, generated model of an instrument to determine a variation. See, e.g., Abstract; col. 1, ll. 11-31; col. 4, ll. 33-42. Rather, Krause '432 compares templates of misaligned bones and properly aligned bones for a surgeon's visual review. Col. 4, ll. 33-42. Therefore, for at least these reasons, the Applicant submits that Krause '432 fails to cure the deficiencies of Krause '174 and the combination fails to teach or reasonably suggest the limitations of the pending claims.

As recited in amended claim 1 and discussed in exemplary embodiments in the specification of the present application, certain embodiments use closed form registration to calibrate deformed instruments in a surgical navigation system. Using closed form registration of an instrument, a solution is overdetermined using multiple data points. That is, the geometry of an instrument may be described specifically. A computer-aided design (CAD) model of the instrument is created. Several fixed points on the instrument are sampled. A mathematical model of where the sampled points should theoretically be located is generated using the CAD model. Using the sampled coordinates and the ideal coordinates, a solution for the position of the sampled points in a reference coordinate frame is determined. Additionally, independent

claims 1, 8, and 14 recite obtaining feedback and recalibrating, techniques not discussed in Krause '432.

Therefore, for at least these reasons and in view of the amended claims, the Applicant respectfully submits that the claims 1-4, 6-9, and 12-20 should be in condition for allowance over the cited art of record.

CONCLUSION

The Applicants submit that the present application is in condition for allowance. If the Examiner has any questions or the Applicants can be of any assistance, the Examiner is invited and encouraged to contact the Applicants at the number below.

The Commissioner is authorized to charge any additional fees or credit overpayment to the Deposit Account of GTC, Account No. 070845.

Respectfully submitted,

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